UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., *Plaintiff/Counter-Defendant,* v. INTUITIVE SURGICAL, INC., *Defendant/Counterclaimant.*	Case No. 3:21-cv-03496-VC Honorable Vince Chhabria **EXPERT REPORT OF DR. T. KIM PARNELL** Complaint Filed: May 10, 2021

Highly Confidential – Subject to Protective Order

TABLE OF CONTENTS

I. QUALIFICATIONS

1. I am a trained Professional Mechanical Engineer (PE) licensed in the State of California. I hold three academic degrees: a B.E.S. in Engineering Science (with Highest Honors) from the Georgia Institute of Technology in 1978, followed by a M.S. and a Ph.D. in Mechanical Engineering from Stanford University in 1979 and 1984, respectively.

2. I am an ASME Fellow and an IEEE Senior Member. ASME is the American Society of Mechanical Engineers and IEEE is the Institute of Electrical & Electronics Engineers. These are the primary professional organizations for Mechanical and Electrical Engineering. There is significant cross-over in terms of combination electro-mechanical devices that need a multi-disciplinary background. I am a Board Member of IEEE-CNSV (Consultants' Network of Silicon Valley). I am also a member of IEEE-EMBS (Engineering in Medicine & Biology), IEEE-CE (Consumer Electronics), IEEE-VTS (Vehicular Technology Society), and IEEE-EPS (Electronics Packaging Society), which focuses specifically on the electronics industry and electronic components, manufacturing, and testing. I have served as an elected officer for several of these groups including as Chair of the IEEE-SCV (Santa Clara Valley) Section (the largest IEEE Section in the world with over 12,000 members in Silicon Valley), Chair of IEEE-CNSV (Consultants' Network of Silicon Valley), and Vice Chair/Treasurer of IEEE-VTS (Vehicular Technology Society). I am also a Member of ASM International (Materials Information Society) and SAE (Society of Automotive Engineers) International. I am Vice-Chair of the NAFEMS Composites Working Group (CWG) which focuses on simulation (Finite Element and other techniques) and on applications of composite materials in all industries.

3. I currently work as an independent consultant through Parnell Engineering & Consulting (PEC). I consult for high-tech industry and legal firms regarding patents, product liability, failure analysis, reliability, and product design/development issues. I have over 30 years

of professional experience using and combining analysis, simulation, inspection, and laboratory measurement to understand and solve engineering problems in a variety of industries and applications. Many of my projects involve products with both electrical and mechanical components and require a multi-disciplinary approach and expertise.

4. I have studied design and ruggedization of a variety of components and systems that must withstand severe service and environmental conditions in service such as medical devices, medical equipment, portable electronic devices, cell phones, and laptops. This experience further includes analyses of materials and material behavior, including elasticity, flexibility, and impact, in addition to deep technical experience with composites, polymeric materials, and manufacturing methods.

5. I have direct experience with manufacturing in multiple industries during my consulting career. This work began in the 1980s and includes various projects up to the present time. These applications include consumer electronics, biomedical, medical device, automotive, petrochemical, paper, metal forming, specialty materials and others. Equipment at issue often involves injection molding, metal forming, stamping, and machining, semiconductor packaging, pipelines and piping components, pressure vessels, sensors and control systems.

6. I began my professional career in 1978 at Bell Laboratories in Indianapolis, Indiana after graduation from Georgia Tech. I was a Member of Technical Staff (MTS) at Bell Labs with a focus on design and development of telephone electro-mechanical components. I worked at Bell Labs before and during my Stanford M.S.M.E. degree, and Bell Labs supported me financially for that degree and I remained on staff.

7. At Bell Laboratories, I worked specifically on keyboard and keypad applications and new design concepts for telephone sets. I built prototypes, studied, tested, and developed

designs utilizing stainless steel domes (caps), silicone rubber domes, piezoelectric polymers, and other novel technologies to simplify design, manufacturing, and assembly in addition to improving reliability. Environmental damage and reduced reliability were of particular concern for telephone sets, especially if the use environment was challenging (dirty, particulates, etc.). The need to develop more reliable and robust keypads and keyboards for these applications motivated this development and the focus on bringing innovative new technologies to the customers in the field. There was a strong emphasis on life-testing at both the component and the system level for all telecom related equipment. Reliability and robust design always represented a central focus throughout Bell Labs and the Bell System. These designs were developed with a keen sense of the importance of the manufacturing and assembly process to the in-service equipment.

8. I took a leave of absence from Bell Labs and returned to Stanford in 1980 to pursue a Ph.D. in Mechanical Engineering and completed that degree in 1984. My work on keyboard and keypad concepts utilizing domes and snap-through buckling behavior for providing a tactile response motivated my Ph.D. research work at Stanford.

9. After Stanford, I then joined SST Systems, Inc. as a Principal Engineer from 1984-1986. In 1986, I joined Failure Analysis Associates, Inc. as a Senior Engineer in the Mechanics and Materials Department. I was promoted to Managing Engineer in 1990. I worked on a wide range of projects as a consultant including aspects such as product failures, product design, and medical device development. The company went public in 1990 as "The Failure Group", but then changed its name to Exponent in the mid-1990's. In 1998, I was promoted to Senior Managing Engineer at Exponent. After 13 years at Exponent, I left to explore the medical device field and joined Rubicor Medical, Inc. in 1999 as Director of Research & Development.

10. When I left Rubicor in 2000, I started offering independent engineering consulting services under Parnell Engineering & Consulting (PEC). I have been an independent consultant from 2000 to the present. During that time, I also worked for MSC Software (2006-2010) in Product Management for finite element simulation software products, consulting, and customer applications.

11. At MSC Software, I was a Senior Manager in the Product Management group, where I contributed in areas such as the User Experience, testing and evaluation of nonlinear simulation tools, and also training. I was recognized as an expert in applications of nonlinear finite element analysis to industry products and challenges. I was an MSC Software technical staff member from 2006-2010 and I consulted with MSC Software extensively from 2000-2018.

12. I was a full-time member of the Mechanical Engineering faculty at Santa Clara University from 2010-2012 and taught classes in Manufacturing, Material Science, Mechanical Design, Finite Element Analysis (FEA), Composite Materials, and Kinematics & Mechanisms. During this time, I served as the Faculty Advisor for several Senior Design Projects. These "real world" Capstone Design Projects encompassed design, system integration, and manufacturing aspects and provided the students with a full product development experience. I also taught graduate courses in Mechanical Engineering at Stanford University from 1995-1996. I have delivered numerous invited presentations, short-courses, and seminars on a range of technical topics to professional organizations and companies. Some of the topics include Mechanical Design for Reliability (MDfR) courses tailored to specific types of products and industries, and Medical Device Technology. I also taught several courses involving the application of simulation and analysis tools and how to better utilize simulation in the design cycle to reduce prototypes, shorten development time, and improve product reliability.

13. My project work includes studies for a broad range of consumer products, equipment, and manufacturing methods. Over the years I have also consulted in the areas of structural mechanics, shock and vibration sensitivity, fracture and fatigue, robust design, and finite element analysis of structures. My practice often encompasses design, failure analysis, forensic investigation, root cause analysis, and reliability issues. My expert work often involves similar issues and often intellectual property matters. Keypad and keyboard concepts include mechanisms, interfaces, and physical design along with volume manufacturing considerations. Recent laptop patent cases involved keyboard technology for moisture resistance, and a laptop display mounting concept to allow the screen to fully pivot or rotate. I also studied enclosures for portable electronic devices for ruggedization and resistance to adverse environments. Hands-on inspection, disassembly, and sometimes destructive evaluations are typical components of projects for portable electronics and medical products.

14. A more comprehensive record of my professional background and technical qualifications is reflected in my curriculum vitae, which is attached hereto as Attachment A. A list of my expert engagements is also included in my curriculum vitae.

15. My opinions and conclusions in this report are based on my years of professional experience in mechanical engineering, failure analysis, and other work in medical devices, medical instruments, consumer electronics, and other sophisticated technology devices. I have relied upon the documents and testimony listed in Attachment B (as well as the materials cited in the text and footnotes of this report). I reserve the right to supplement or amend my report as new information becomes available.

16. I am not currently and have not previously been employed by Surgical Instrument Service Company, Inc. ("SIS"). Counsel for SIS retained me to provide my independent and

to confirm that they continue to function identically to new EndoWrists. On the other hand, Intuitive has never tested EndoWrists repaired by Rebotix.[53]

VI. THE REBOTIX REPAIR PROCESS IS MUCH MORE THAN A "RESET" AND ADEQUATELY ADDRESSES THE EFFECTS OF WEAR AND TEAR THAT ACCRUE DURING ENDOWRIST USAGE.

68. According to Dr. Howe, "'although SIS refers to the 'reset' service Rebotix provides as a 'repair,' Rebotix simply devised a method that intercepts communication between the robot and the instrument in order to circumvent the usage limits implemented in each EndoWrist instrument, without adequately addressing the effects of wear and tear that accrue during instrument usage." Howe Report ¶ 14. Dr. Howe then provides a four-paragraph "Overview of Interceptor Technology" without mentioning the steps of the Rebotix process that "address the effects of wear and tear that accrue during EndoWrist usage." I discuss these steps below.

69. In my report below, I discuss the Rebotix repair process that I personally observed at the Rebotix facility. I further discuss the Rebotix repair process and some of the supporting documentation in more detail. I understand that EndoWrist repairs performed for SIS customers, prior to Intuitive shutting down SIS's EndoWrist repair business, were performed by Rebotix.[54]

70. I understand that (a) SIS was in negotiations with Rebotix to perform that repair process at SIS facilities,[55] and (b) in connection with those negotiations, Rebotix did a test run of that process at SIS's facility for a major EndoWrist repair customer, Banner Health.[56]

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[53] DeSantis depo tr., 245:6-11 ("Q. Intuitive has not done testing of any kind to determine whether Rebotix's refurbished EndoWrists can safely be used with the da Vinci robot in surgery; true? A True. We've not done V&V testing, life testing on their instruments, no.")

[54] K. Johnson 30(b)(6) depo tr., 19:5-20:1, 33:22-34-11.

[55] K. Johnson 30(b)(6) depo tr., 33:9-18; Posdal 30(b)(1) depo tr., 28:13-29:24.

[56] Posdal 30(b)(1) depo. tr., 30:5-15.

A. Incoming Inspection and Screening

71. When an EndoWrist is received from a customer to be repaired, Rebotix logs that EndoWrist in its inventory. Rebotix then scrubs, flushes, disinfects, and sterilizes that device, as shown in the *EndoWrist Instruments Reprocessing Wall Chart* below.

Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

72. After this initial process of ultrasonic cleaning and sterilization, Rebotix performs an initial inspection of the device. As part of that inspection, Rebotix removes the housing at the

proximal end of the EndoWrist. A Rebotix technician then performs an initial visual inspection of the entire device to scan for any indication of damage. Rebotix also checks the use counter to determine the number of uses remaining on the device.

This photo shows a selection of the EndoWrists that Rebotix received. The housing on each EndoWrist is removed. The bottom EndoWrist has had the cable system detached for illustration and examination (this is not a standard repair step). Rebotix's Interceptor assembly appears at the top of the image. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

73. After the initial visual check, a Rebotix technician uses an optical microscope at high magnification to examine the tool end of the EndoWrist (the scissors, graspers, etc), the exposed cables, and the pulley system at both the proximal and distal ends of the device. During this step, Rebotix looks for signs of cable fraying, cables misaligned with pulleys, pulley damage, damage to the main tube of the instrument, and any corrosion or contamination on the instrument bearings or the cables.

74. In addition to the visual inspection, when assessing whether the instrument is a candidate for repair, Rebotix operates each drive component through its full range of motion. During this process, Rebotix may determine that a cable has slipped off a pulley and become misaligned or that the device is otherwise unable to operate in its full range of motion.

75. For electrosurgical instruments, Rebotix performs the "Hipot Test" test sequence to ensure that the instruments' insulation and electrical isolation is functioning as required. The test sequence indicates whether there is any damage or breakdown in the electrical insulation and isolation of the device or another issue that prevents the electrosurgical components from functioning safely in terms of their electrical behavior.

This is a photo I took of the Dielectric Withstand Tester that Rebotix uses to run the "Hipot Test" to verify the insulation of electrosurgical EndoWrists. The programmed test sequence results in either a Pass or a Fail result. If the test reads "Fail" instead of "Pass," the instrument is not a candidate for repair. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

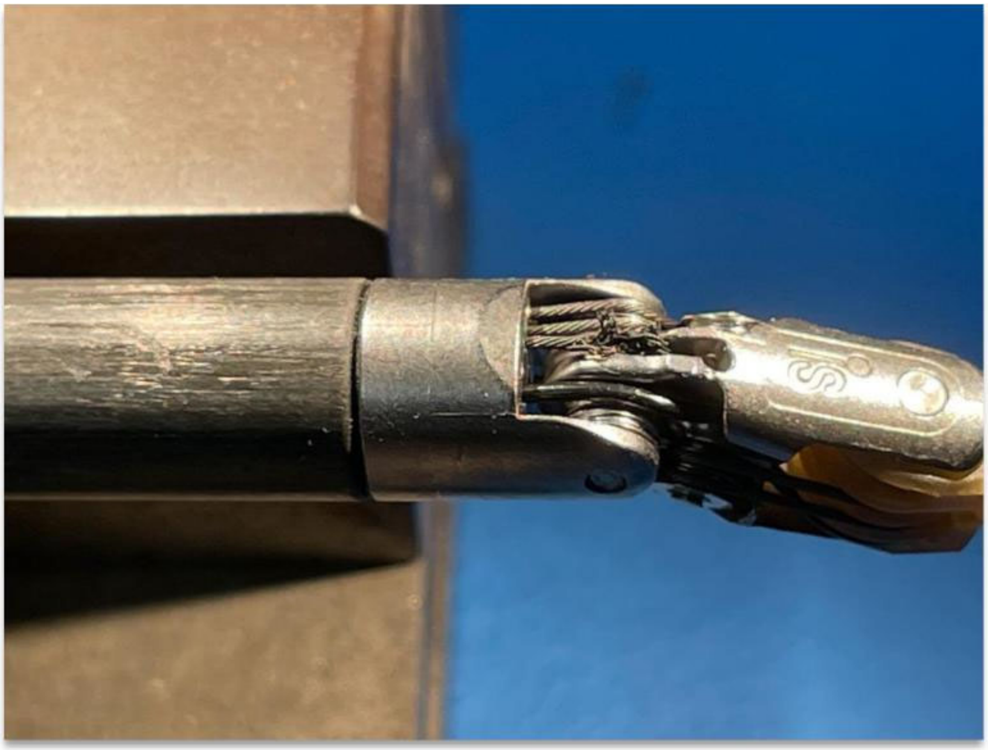
76. These initial inspections are meant to identify whether there is any existing damage to the EndoWrist device that indicates that the specific EndoWrist is "Unsuitable for Repair." Instruments can be "Unsuitable for Repair" due to frayed or broken cables, damage to the pulley

system (including sheared pins or broken bearings), or due to broken instrument tips. Similarly, if there is any damage to an electrosurgical instrument's insulation or the instrument fails the electrosurgical insulation/isolation test, the instrument will not be a candidate for repair.

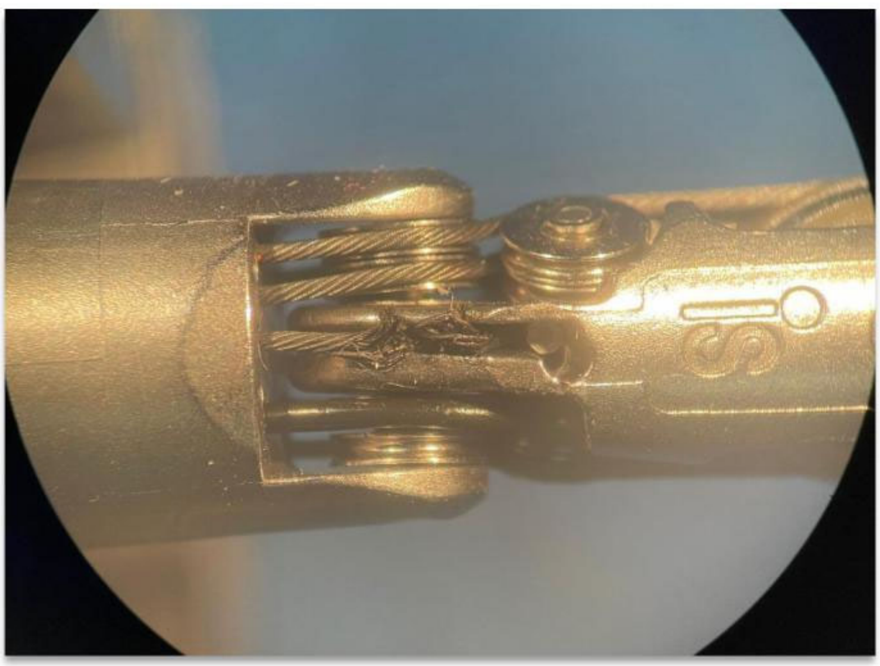
77. When Rebotix determines that an instrument is "Unsuitable for Repair," Rebotix then notifies the hospital that submitted that EndoWrist of that determination. At that point, the device may be returned to the customer or remain in inventory at Rebotix and be labeled as "non-repairable."

78. I inspected several devices at Rebotix that were deemed to be "Unsuitable for Repair." As an example, an EndoWrist with a severed cable was not a repair candidate.

This picture is of an EndoWrist that Rebotix received from a hospital customer that was deemed "Unsuitable for Repair" due to cable damage. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.



This is a photo I took of the same EndoWrist. The frayed cable is clearly visible at the distal end of the EndoWrist. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

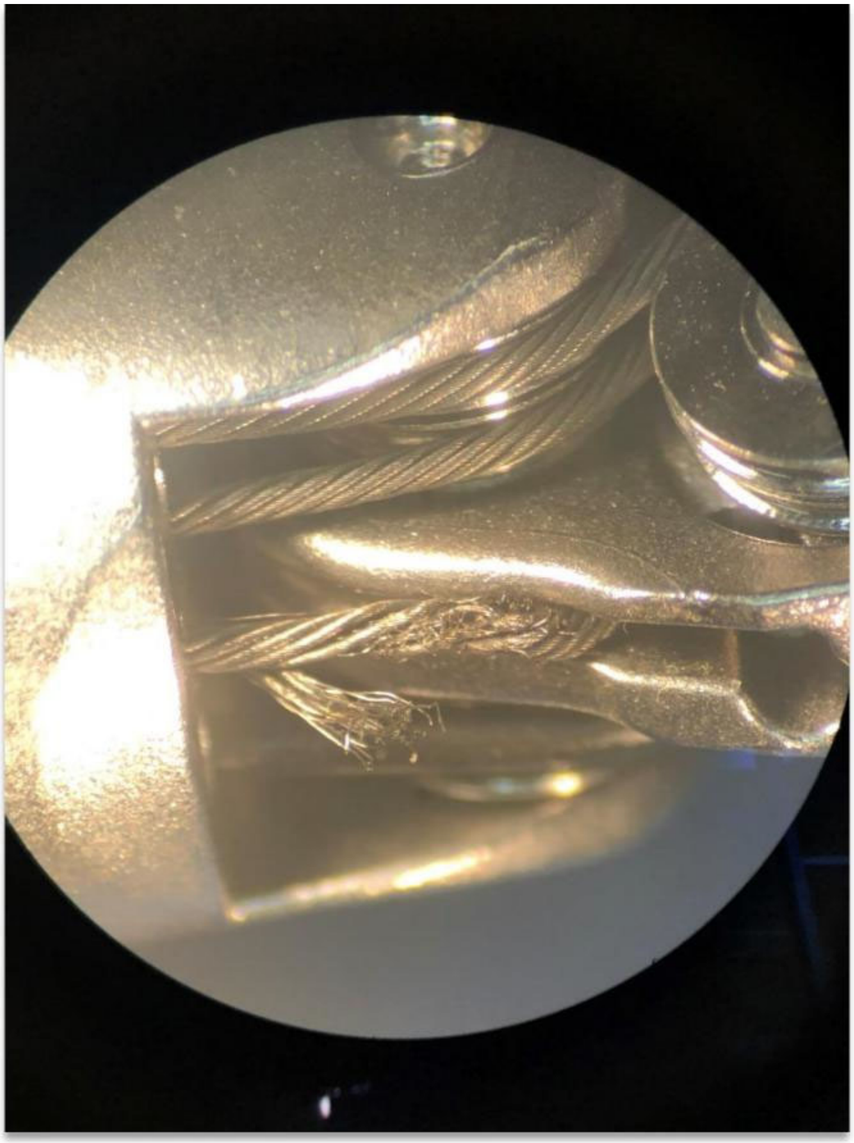


This is a picture of the same EndoWrist under an optical microscope. The cable tear is clearly visible. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

79. This EndoWrist still had remaining uses on the use counter, indicating that the failure had occurred before the instrument had reached its maximum number of uses. This instrument was received by Rebotix from a hospital that performed a visual inspection prior to surgery.

80. As another example, a PK dissecting forceps with four remaining uses was found to be unsuitable for repair due to a cable break.

Parnell, in-person visit to Rebotix facilities on August 10th, 2021.



Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

81. In my examination of the EndoWrists that were "Unsuitable for Repair," I did not detect damage due to wear on the instrument. For example, in the cables above, one of the cables in each instrument experienced a break, while the others were fully intact with no signs of fraying. The discrepancy between the cables (one displaying significant damage and the others showing no sign of wear) indicates that one cable was subject to damage from an external object or from

misuse. Other instruments with cables that I examined similarly reflected external damage and breakage, rather than normal wear.

82. This incoming inspection and screening is critical in order to identify EndoWrists with damage that are "Unsuitable for Repair."

B. Interceptor Installation for Use Counter Reset

83. Once an instrument has been identified as a candidate for repair, Rebotix performs a use counter reset by installing the Interceptor component. By doing so, Rebotix restores the use counter to its original value. In other words, if the use counter for an EndoWrist instrument is initially set to ten uses, Rebotix will reset the use counter to the same value of ten uses. By setting the counter back to the same value as the original, Rebotix ensures that the EndoWrists will be sent in for inspection and repair after that limited number of uses. By contrast, traditional laparoscopic instruments do not have a use counter and therefore, are sent in for inspection and repair only when necessary, but not at regular intervals.

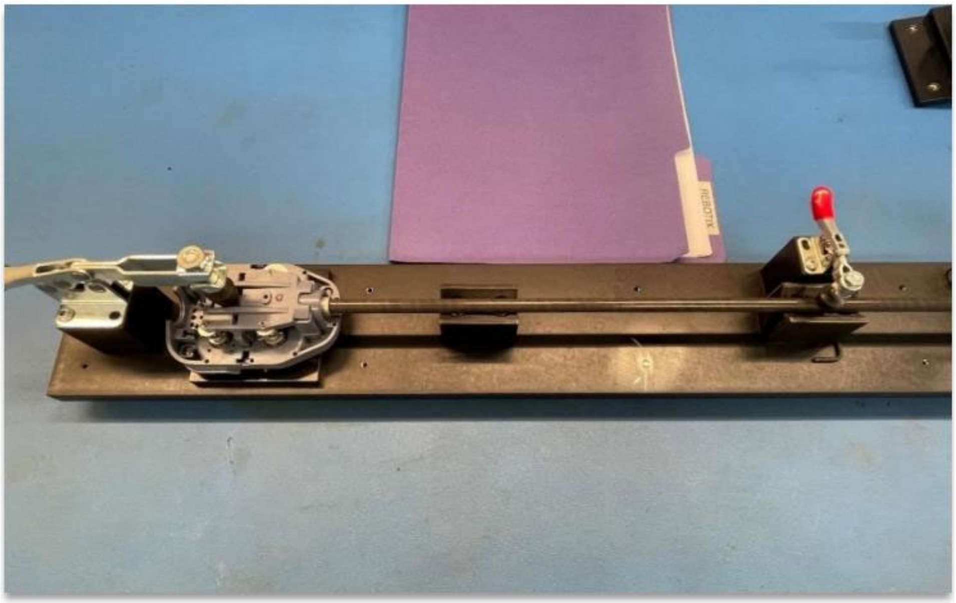
C. Adjustment and Repair

84. After the Interceptor is installed, Rebotix then performs any needed repairs on the tool end of the EndoWrists, such as sharpening scissors, aligning graspers, or ensuring sufficient tightness on needle drivers. Rebotix then makes any needed adjustments to the cables. Rebotix places the EndoWrist in a special fixture and locks the device in its neutral position. This tensioning process involves (a) adjustment of the cable tension, and (b) testing the EndoWrist range of motion and no-load torque for each drive wheel to ensure that the tension is appropriate for surgical use. I personally tensioned the cables on an EndoWrist and was able to readily identify over-tensioning or under-tensioning of the cable. An under-tensioned cable fails to communicate movements precisely to the distal end, while an over-tensioned cable requires excessive additional

torque on the drive wheels at the EndoWrist proximal housing to operate. Indeed, this process is similar to the process utilized by Intuitive for cable tensioning of its Si EndoWrists, while for Xi EndoWrists a similar process is performed using an automated fixture.[57]

Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

[57] Duque 30(b)(1) depo. tr., 136:24-146:13.



The Rebotix designed fixture for cable adjustment and tensioning holds the EndoWrist steady in its neutral position and allows for cable tension to be calibrated. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

D. <u>Outgoing Inspection and Evaluation</u>

85. Finally, Rebotix conducts a series of tests on the instrument as part of an outgoing evaluation.[58] As part of that process, Rebotix verifies that the use counter reset was successful and that the instrument shows the original specified number of uses. Rebotix also evaluates whether the instrument's motion is functioning as expected, and whether the tool end of the instrument is performing appropriately (for example, cutting tissue or grasping). In addition, Rebotix performs a second round of testing for electrosurgical EndoWrists in order to verify the integrity of the electrical insulation and isolation of the device.

86. If the EndoWrist passes all of the testing and inspection processes and is deemed fully functional, it is then subjected to another full cleaning process, which includes scrubbing,

[58] REBOTIX123448; REBOTIX134750-REBOTIX134754; REBOTIX134655-134656.

flushing, disinfection, and sterilization. Although EndoWrists are not shipped back to hospitals as sterile, and thus need to be reprocessed upon receipt, this cleaning process ensures that any debris or particulate matter is removed from the EndoWrist.

87. The EndoWrist is then repackaged and returned to the customer. Only an EndoWrist that satisfies both the Rebotix initial quality inspection and the Rebotix final inspection protocol will be returned to the hospital that originally sent that EndoWrist to Rebotix for repair.

E. Repair Process Returns EndoWrists to Original Functional Specifications

88. When Rebotix repairs an EndoWrist instrument, it performs a series of steps that return the EndoWrist to its original functioning specifications. As part of that process, it sharpens scissors, tightens loose cables, and ensures that the instrument performs in a manner equivalent to a new instrument.

89. Rebotix then installs the Interceptor chip, which resets the use counter to its original specification.[59] Rebotix does not increase the use counter to a value beyond the initially specified number of uses. And Rebotix does not otherwise alter the function of the instrument in any way.

90. The equivalent performance between EndoWrists repaired by Rebotix and those sold new by Intuitive has been confirmed by hospitals that have used the Rebotix repair service.

91. When Pullman Regional tested Rebotix-repaired instruments, they determined that "[t]here was no difference than the non-reprocessed instruments," and "didn't have any issues" with the Rebotix-repaired instruments.[60] None of the members of the surgery team at Pullman were able to identify any difference between the Rebotix-repaired EndoWrists and EndoWrists that had not been repaired or serviced by Rebotix.[61] In follow up interviews with the surgical teams that

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[59] *See, e.g.,* REBOTIX162185
[60] Harrich depo tr., 37:1-25.
[61] *Id*. at 38:9 – 39:3.

used Rebotix-repaired EndoWrists, Pullman learned "[t]hat the instruments still worked just like the nonrepaired ones. There was no difference."[62]

VII. INADEQUACIES OF THE ENDOWRIST USE COUNTER

92. Dr. Howe asserts that the use counter is an "essential part of the specifications for the EndoWrist instruments" (Howe Report ¶ 23) that ensures that EndoWrists can be used safely. This assertion is false.

93. First, although Dr. Howe contends that the Rebotix repair process does not address "wear and tear" (Howe Report ¶ 14), it is actually Intuitive's use counter that merely measures how many times an instrument has been "used" in a surgery, as opposed to the wear the instrument experiences during the surgery. An instance of "use" itself is poorly correlated with wear, because it does not take into account the time or complexity of the "use" or surgery. Moreso, Intuitive relies merely on the number of "uses," even though it measures and stores data that could easily be used to more accurately measure actual usage, e.g., actual length of time and intensity of the EndoWrist usage during a surgical procedure. As a result, the use counter artificially cuts short the useful life of EndoWrists.

94. Second, although Dr. Howe contends that "[a]n essential part of the specifications for the EndoWrist instruments is a limitation on the number of times each instrument can be used for surgical procedures" (Howe Report ¶ 23), Intuitive's use counter does not take into account the mishandling or misuse of an instrument. An instrument can fail due to mishandling on its first use or on its twentieth.

95. Third, although Dr. Howe contends that "Intuitive's usage limits . . . [are] amply supported and validated by scientific testing" (Howe Report ¶ 7) and that its EndoWrist "designs

[62] *Id*. at 40:2-8.

are life tested" (Howe Report ¶ 32), Intuitive did not adequately perform failure mode testing. Rather, Intuitive's testing on the appropriate number of uses validates a preset target provided by its marketing department, rather than establishing the maximum number of uses an instrument can actually undergo before experiencing a failure.

96. Fourth, although Dr. Howe contends that "Intuitive's usage limits 'are critical for patient safety" (Howe Report ¶ 7), the use counter indicates only that the proximal end of the EndoWrist, which contains the use counter chip, was mounted to the da Vinci robot and entered into "following" mode, thus recording a use and decrementing the use counter. There is no check on the condition of the instrument or an assessment of the instrument's operation; those checks must be performed by the hospital team. The shaft and distal tool end could be totally removed from the instrument and the use counter would still be decremented if the surgeon attempted to operate the instrument. In this sense, the use counter is meaningless as an indicator of the EndoWrist's safe operation.

A. Use counter does not measure actual wear experienced by instruments in surgeries.

1. Surgical procedures vary radically in amount of time and complexity, and therefore result in different amounts of load and stress placed on each instrument used during surgery.

97. All surgeries, including laparoscopic surgeries, range significantly in the amount of time and intensity involved in the procedure. For example, one study highlighted that the "range of operating times is great," and that there is a "relative lack of predictability in procedure times." The study concluded that timing for the most common gynecological laparoscopic procedures ranged between 10 and 400 minutes.[63] There are additional significant ranges in individual

[63] Shushan A, Mohamed H, Magos AL. How long does laparoscopic surgery really take? Lessons learned from 1000 operative laparoscopies. Hum Reprod. 1999 Jan;14(1):39-43. doi: 10.1093/humrep/14.1.39. PMID: 10374091.

procedure times for other types of surgery. For example, surgery for endometriosis might range from 10 to 240 minutes, while a hysterectomy might range between 25 and 400 minutes.[64] And procedure times are generally similar between robotic and non-robotic laparoscopic procedures. For example, one study determined that total operating time "did not differ significantly" between robotic assisted and non-robotic assisted laparoscopic cholecystectomies.[65]

98. Further studies have outlined the significant range in operative time from patient to patient even in the same type of surgeries. One study examining laparoscopic colon surgeries found ranges between 50 and 300 minutes for Ileocecal colectomies, between 62 and 330 minutes for sigmoid colectomies, and between 130 and 590 minutes for total abdominal colectomies.[66] This significant range in the length of surgical time even between patients undergoing the same surgery further illustrates the lack of uniformity in the time that instruments are used during surgery.

99. Instruments used in surgeries can also be used in varying ways. Some instruments might be used for complex anastomosis (sewing or suturing), while other instruments might be used to grasp or hold tissue in a single position during the surgery.[67] Instruments might be used for short periods of intense usage that place great strain on the instrument, or they might be used for long periods with minimal strain placed on the instrument.

100. All of these variables show why there is a variance in frequency of repairs for traditional laparoscopic instruments—they require repair service at different rates depending on how they are used in surgery. As discussed above, Bob Overmars testified that traditional laparoscopic instruments may be used "dozens to hundreds" of times before being repaired, and

[64] *Id*.
[65] Ruurda, Jelle P., et al. "Analysis of Procedure Time in Robot-Assisted Surgery: Comparative Study in Laparoscopic Cholecystectomy." *Computer Aided Surgery*, vol. 8, no. 1, 2003, pp. 24–29., doi:10.3109/10929080309146099
[66] Scheer, Adena, et al. "Laparoscopic Colon Surgery: Does Operative Time Matter?" *Diseases of the Colon & Rectum*, vol. 52, no. 10, 2009, pp. 1746–1752., doi:10.1007/dcr.0b013e3181b55616.
[67] McGrogan depo tr., 26:8-25.

that the functional characteristics of the instrument, such as "lack of grip of the instrument jaws," and "dull scissors" determines when they require repair.[68] Therefore, an instrument that is heavily used during a few long and intense surgeries will experience more significant wear than an instrument that is used in a much larger number of shorter and less intense surgeries.

101. EndoWrists are similarly used for different amounts of time during surgery—they can be used for a few seconds, a few minutes, or for multiple hours.[69] They are also used in different ways during surgery.[70]

102. A system designed to accurately track the actual wear that an EndoWrist experiences in surgery would consider, at a minimum, both the length of time that instrument has been used, and the complexity of the tasks the instrument performed, in addition to potentially other factors. Intuitive has acknowledged the obvious point that to accurately reflect the wear that an instrument has experienced, one would want to take into account at least the length of time that an instrument was used in surgery and the complexity of the tasks performed in that surgery.[71]

2. <u>The use counter does not account for the length of time or complexity for which an instrument is used during surgery.</u>

103. The use counter decrements a single life as soon as the EndoWrist is manipulated from the surgeon console regardless of the time an instrument has been used or the complexity of the instrument's use during surgery. It follows that the remaining use count does not in any way indicate how or for how long the EndoWrist was used in prior surgeries.

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[68] Overmars depo. Tr., 98:10-16.
[69] McGrogan depo. tr., 24:11-17.
[70] *Id*. at 26:8-25.
[71] *Id*. at 32:9-22.

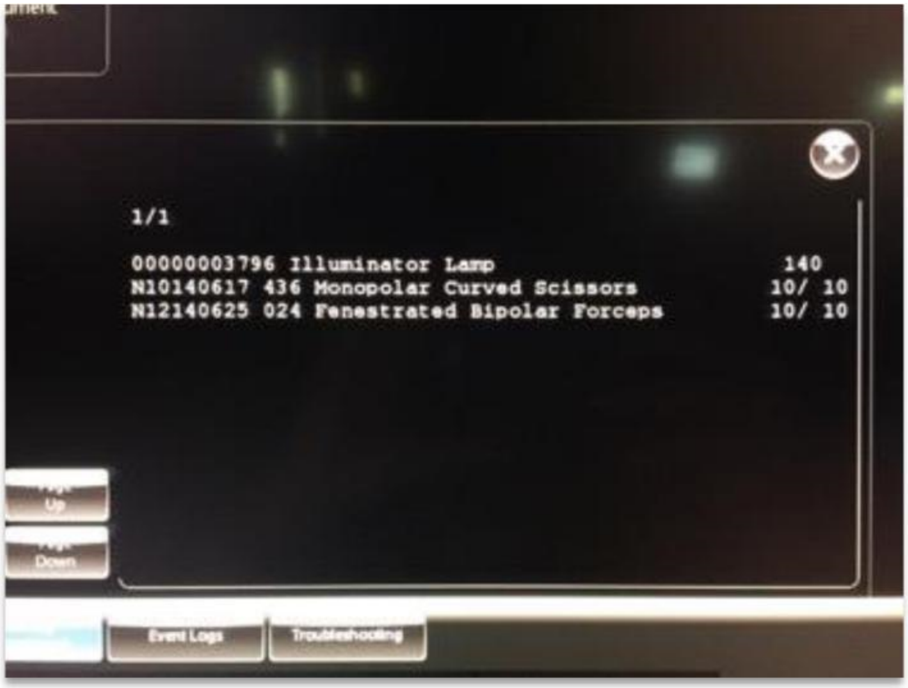

Image from Da Vinci Vision Cart

104. As shown above, the only information that the use counter displays is the serial number, the original number of uses and the remaining number of uses. Once an EndoWrist instrument is attached to the da Vinci robot and used in surgery in any way, a life is subtracted from the use counter.[72] That is the case whether an instrument is used for ten seconds or two hours inside a patient's body.[73]

105. That the dramatic time differences in surgeries discussed in the previous section—ranging between 10 minutes and almost 10 hours—are completely disregarded by Intuitive's use counter is confirmed by Anthony McGrogan, an Intuitive Vice President of product design. At his deposition, McGrogan was asked about two hypothetical EndoWrist instruments: (1) one instrument was used for one minute in each of its ten uses before the use counter read zero and (2) another was used for one hour for each of its ten uses before the use counter read zero. Even though

[72] McGrogan depo tr., 17:13 –18:6.
[73] *Id*.

one instrument was only used for ten minutes in surgery and the other was used for ten hours, Intuitive requires each of those instruments to be thrown away because the use counter in both has been decremented to zero:

> Page 24
> Q. Now, let's assume that there is one
> instrument that's used ten times for about an hour
> Page 25
> per surgery.
> Okay? Are you with me?
> A. Yep.
> Q. That instrument, according to Intuitive, is
> safe to be used for ten uses; right?
> A. Yes.
> Q. After those ten uses are up, Intuitive
> would tell the hospital you need to throw this
> instrument away; right?
> A. Right.
> Q. Now, let's take another instrument, same
> instrument. Let's use a cold grasper. It's used
> for one minute during surgery at different times.
> A. M-hm.
> Q. Was that a "yes"?
> A. Yes.
> Q. Intuitive would also tell the hospital to
> throw that instrument away after ten uses; right?
> A. Yes.
> Q. So the first instrument would have been
> used actually in surgery for ten hours; right?
> A. M-hm.
> Q. "Yes"?
> A. The total surgical time is, I believe,
> ten -- yes, ten hours.
> Page 26
> Q. The second instrument would have been used
> in surgery for ten minutes; right?
> A. Yes.
> Q. Intuitive would tell hospitals that each
> one of those instruments needs to be thrown away;

right?
A. That's true.[74]

106. Further, the complexity of different surgical procedures and the complexity of what each EndoWrist instrument is used for is not reflected in the uses remaining on the use counter. Mr. McGrogan confirmed that hospitals are not required to distinguish between simple and complex procedures.[75] For example, a grasper could be used to grasp tissue a single time during a surgery, or dozens of times. In either case, the use counter will decrement a single life from the instrument, failing altogether to reflect the difference in actual usage between these two instruments.

107. Intuitive's purported inclusion of the use counter is to ensure patient safety, but the use counter itself fails to accurately take into account the key metrics of instrument wear. Measuring the life of an instrument should take into account both the time an instrument has been used and the complexity of the procedures for which the instrument was used—as acknowledged by Mr. McGrogan.

Q. Well, one way that Intuitive could measure
the life left in an instrument would be to measure
the instrument based on the time that it's been used
in surgery; right?
A. I think we talked that time is not a good
metric for measuring wear and tear.
Q. Well, the time takes into account how --
how long an instrument has been used in a given
procedure; right?
A. That's all it takes into account.
Q. Another thing that you might want to take
into account would be the complexity of what the
instrument is being used for right?
A. That's right.

[74] McGrogan depo. tr., 24:24 – 26:7
[75] McGrogan depo. tr., 28:21-25.

MR. RUBY: Object to the form of the question. But it's been answered.
///

Page 33

BY MR. ERWIG:
Q. I'm sorry. I didn't get your answer.
A. I said yes.[76]

Page 33

Q. Now, a decrementing of the life on a use counter, that doesn't take into account either the time that the instrument has been used in surgery or the complexity of what the instrument did during the surgery; right?
A. That's right, as far as I know. Again, I don't know the details of the algorithm. But, generally speaking, if you use it in surgery, it's going to get decremented.
Q. That's the same whether it's been used for ten simple short procedures or ten --
A. Yes --
Q. -- complex, long procedures; right?
A. Yes, yes.[77]

108. Accordingly, the Intuitive use counter does not provide the surgeon with any practical or relevant information about the instrument's actual usage, such as time of use, how the instrument was used, number of particular movements, type of movements, types of procedures, forces experienced, whether an instrument malfunctioned, or whether an instrument was misused or abused.[78] Nor does it account for extreme use cases that might require replacement after a single use.[79]

[76] McGrogan depo. tr., 32:9–33:3.
[77] McGrogan depo. tr., 33:4-17
[78] Mahal Report at ¶ 65.
[79] Mahal Report at ¶ 66.

109. A result of the Intuitive EndoWrist use counter's failure to accurately track an instrument's useful life is that EndoWrists can and do fail prior to the use counter expiring. By the same token, EndoWrists that reach the maximum number of uses may still be capable of safe use beyond that number. This has been borne out in the actual use of EndoWrists--hospitals encounter EndoWrist failures before the use counter has expired, and also have EndoWrists with one remaining use on the use counter that show no signs of wear or failure.[80]

110. Intuitive measures and stores the electrical current of the motors that operate the cable and pulley systems of the EndoWrists during a procedure, which in turn is proportional to the motor torque.[81] Based on this data, Intuitive has the ability to monitor how long an EndoWrist was actually used during surgery as well as the types of forces and movements that the EndoWrist experienced during each surgery.[82] In fact, Intuitive uses this data to identify root causes for EndoWrist failures.[83] Nonetheless, despite having data available that could be used to more accurately determine wear and tear, Intuitive chooses to ignore this information in favor of its simplistic and arbitrary use counter.[84]

111. Traditional laparoscopic instruments do not have use counters.[85] Instead, the instruments are routinely inspected, repaired, and continue to be used.[86] And if an instrument cannot be repaired, that instrument is discarded and no longer used in surgeries.

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[80] Harrich depo. tr., 41:12-17. Harrich depo. tr., 59:10-24, Harrich depo. tr., 165 12:20, Donovan depo. tr., 34:20-25, Donovan depo tr., 145:21-146:6.
[81] Duque 30(b)(6) depo. tr., 14:11-15:11.
[82] Duque 30(b)(6) depo. tr., 17:22-18:6.
[83] Duque 30(b)(6) depo. tr., 17:6-18:14.
[84] Duque 30(b)(6) depo. tr., 19:25-20:10.
[85] Mahal Report at ¶ 64.
[86] Donovan depo. tr., 40:9-13, Harrich depo. tr., 45:10-20.

112. Hospitals measure wear on instruments by assessing whether they are performing the required function in surgery. Evidence in these litigations shows that EndoWrists frequently performed no differently by the end of their tenth use than they had on their first use. For example:

> Q. You stated that you believed EndoWrists had additional lives on them before you had to dispose of them when they reached their maximum use restrictions; is that right?
>
> A. That's correct.
>
> Q. Why did you believe that EndoWrists had additional lives on them?
>
> A. Well, on the end of the tenth life, it wasn't working any different than it had been on the first life. There was no complaints by the physicians. If there were any, we'd take the instrument out of service or send it back in to Intuitive for repair if it still had lives left on it.
>
> So if it's a grasper, it's a grasper. Is it grabbing the tissue like you think it should? As the physician says, it's feeling that tactile touch. You can't actually feel the touch, but on a console.
>
> Page 36
>
> But it's grabbing the tissue. They're liking what they're seeing. They're liking what they're feeling. So the instrument can still continue to be used.
>
> Q. Is that how you determine whether a traditional laparoscopic device should continue to be used as well?
>
> A. Yes, the functionality of it.[87]

This serves as further evidence of how Intuitive's use counter fails to measure actual instrument wear.

[87] Harrich depo. tr., 35:9 – 36:8

B. <u>The use counter does not take into account mishandling or misuse.</u>

113. Misuse, mishandling, or improper cleaning can occur at any time, including before an instrument's use counter reaches zero. For example, during my visit to the Rebotix facility, I saw numerous instruments that had experienced a failure prior to their use counter expiring. Those failures included snapped tool ends, fully cut cables, frayed wires, and broken instrument shafts.

114. The EndoWrist use counter does not take these failures into account or track whether those failures have occurred.[88] An instrument can have five or six remaining uses, but misuse can cause broken scissors, bent graspers, or broken cables. The only way to accurately determine whether an instrument has been misused or mishandled is through visual inspection and testing. The use counter does not in any way ensure that an instrument has not been subject to mishandling or misuse.

C. <u>Intuitive's life testing is designed to validate an arbitrarily set use limit set by marketing, rather than to establish the failure point of an instrument.</u>

1. <u>To accurately establish a use limit or failure point, tests would need to actually test instruments to failure.</u>

115. In my experience, studying the failures experienced by mechanical components and medical instruments, testing instruments to failure and observing at which points those failures occur, all help to establish the potential range of life for an instrument. Establishing and identifying the potential failure modes accurately is important.[89]

116. As an example, in a sample of ten tested instruments, testing each to failure would involve setting certain failure conditions (such as breaks in instrument cables or dulled scissors)

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[88] Mahal Report at ¶¶ 65-66.

[89] *See, e.g.,* "Engineering Failure Analysis, Fatigue & Mechanical Tests: DNV Labs." *DNV*, www.dnv.com/oilgas/laboratories-test-sites/engineering-failure-analysis-fatigue-tests-and-mechanical-tests-dnvgl-labs-hovik.html., and "Failure Analysis Testing: Engineering Failure Analysis |." *Stress Engineering Services, Inc*, 14 Feb. 2020, www.stress.com/capabilities/materials-engineering/failure-analysis/.

and observing at which point each of the instruments experiences a failure. In that ten-instrument sample, one instrument might fail at use 50, and nine others might fail after use 200.

117. By contrast, halting tests after a certain number of uses produces skewed results. In the above example, if testing for the nine other instruments were arbitrarily halted at use 60, the results of the testing would indicate that the instruments had a lower acceptable life. Testing to failure produces an accurate statistical analysis of instrument failures because it actually establishes the range of failure conditions and the useful life of an instrument.

2. <u>Intuitive's testing is designed to validate target lives set by marketing and does not accurately assess the instrument's failure point.</u>

118. Intuitive's life testing does not accurately assess the useful life of an instrument. Instead of attempting to establish the maximum number of lives that an instrument can be safely used, Intuitive's testing aims to statistically validate a preset target limit.

119. The initial targets for an instrument's use counter are set by marketing.

Page 35
Q. Now, when Intuitive is first considering
what it's going to be setting the lives at,
marketing is involved in that process; right?
A. Marketing is involved to the extent that
they set goals for engineering.
Q. For example, marketing might set a goal of
ten lives for an instrument; right?
A. That's an example, yes.
Q. And then engineering would try to design an
instrument that would meet that ten-life goal;
right?
A. Yes.[90]

Q. But when a new instrument is being
developed for a customer, marketing is setting the
target for that instrument before there's any

[90] McGrogan depo. tr., 35:9-20

testing that's conducted; right?...
THE WITNESS: Marketing sets a goal for
reposable instruments.
BY MR. ERWIG:
Q. Then engineering designs and tests an
instrument to try to achieve that goal; right?
A. That's right.[91]

And the testing performed on an instrument to establish the number of lives on the use counter takes place only after those initial targets have been set by marketing and provided to engineering.

Q. Now, for formal life testing, formal life
testing is performed after there's been a particular
target set by marketing; right?
A. Typically, yes, formal life testing.
Q. That's ultimately what's used when
Intuitive sets the life counter; right?
A. Yes.[92]

120. Intuitive's Weibull Design of Reliability aims to test a sample of instruments to confirm that instruments will reliably meet a pre-set life target.[93] Intuitive deliberately chooses to stop its life testing protocols shortly after the instruments being tested pass the target number of lives. For example, during Intuitive's life testing for extended life instruments, it prematurely halted testing instead of testing all instruments to failure.[94] For Intuitive's initial life testing of many of its highest-usage Xi EndoWrists, it stopped testing once it justified 10 uses even though none of the instruments experienced a failure.[95]

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[91] McGrogan depo. tr., 64:5-19 (objection omitted)
[92] McGrogan depo. Tr., 65:19-25
[93] *See, e.g.,* Intuitive-00542459 – Intuitive-00542461.
[94] Intuitive-00642553.
[95] Duque 30(b)(6) depo. tr., 63:11-64:18; Duque 30(b)(1) depo tr., 115:19-117:15; Duque Ex. 268 (Intutiive-02066979) at 02067029 (stopping testing at 13 life cycles with no failures), 02067033 (stopping testing at 15 life cycles with no failures), 02067034 (stopping testing at 15 life cycles with no failures), 02067038 (stopping testing at 13 life cycles with no failures), 02067039 (stopping testing at 10 life cycles with no failures).

128. Rather than relying on the use counter, hospitals examine EndoWrists before surgery to determine whether they are safe for use.[107] When hospital technicians recognize issues with an EndoWrist, it will not be used in surgery.

129. Numerous instruments at Rebotix's facility that were received from hospitals and were ultimately deemed "Unsuitable for Repair" had remaining uses on the use counter. For example, the instruments I examined with broken cables all had remaining uses. The use counter would not prevent those instruments from being used in surgery.

VIII. ANY "DIFFERENCES" BETWEEN OTHER INSTRUMENTS REPAIRED BY SIS AND ENDOWRISTS DO NOT IMPACT SIS'S ABILITY TO REPAIR ENDOWRISTS

130. Dr. Howe opines that "any familiarity SIS has with maintenance and repairs to medical devices that use cables and pulleys, like flexible endoscopes, beds, and orthopedic limb holders, is insufficient to support the safety or reliability of the reset service Rebotix performed for SIS customers." Howe Report ¶ 15.

131. In support of that opinion, Dr. Howe discusses purported differences between the end uses of cabled instruments that SIS has previously repaired and the end use of EndoWrists, focusing on speed of operation and number of cable cycles for a typical use (Howe Report ¶¶ 39-41), exposure during reprocessing (Howe Report ¶¶ 41, 43), and the relatively small size of EndoWrist cables and pulleys (Howe Report ¶ 42).

132. There are numerous errors in Dr. Howe's comparison of different cabled instruments.

133. Dr. Howe speculates, without even discussing the respective reprocessing protocols or any other support, that the cables within EndoWrists are subject to more rigorous reprocessing

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[107] Harrich depo. tr., 40:12-25, Donovan depo. tr., 33:23-34:9, 35:16-21.

than flexible endoscopes because "the [flexible endoscope] cable are contained entirely within the instrument and thus are not exposed to the harsh chemicals that cause damage." Howe Report ¶¶ 41, 43. However, flexible endoscopes may also be exposed to chemicals during reprocessing, for example, if the protective seal around the cables is damaged.[108] What is critical, and what SIS ensures for flexible endoscopes, is that a cable that has been reprocessed is inspected for wear such as corrosion, and then cleaned and repaired or tensioned if necessary.[109]

134. Dr. Howe focuses on the loading of EndoWrist cables (Howe Report ¶ 42), without ever addressing that the loading conditions of cables of flexible endoscopes, beds, and limb holders create conditions that EndoWrists typically do not experience. For example, while EndoWrist cables are typically actuated briefly for a series of movements, cables of a flexible endoscope have to accurately hold a position for an extended period of time and accurately navigate through tortuous anatomy. Moreover, flexible endoscopes have cables that are typically much longer than an EndoWrist cable, sometimes as long as six feet from the proximal controls to the distal tip. Further, flexible endoscope cables are angled through multiple unpredictable turns through the specific target anatomy for imaging and sample collection. While an EndoWrist cable may not be engaged for an entire surgery or even most of a procedure, the cables of a flexible endoscope may be in use throughout the procedure with varied strains and stresses for an extended period of time. The cables of beds and limb holders may undergo extreme and varied conditions as they are used for a variety of patients and situations, under less controlled conditions than an EndoWrist. These applications are all examples of long-term SIS experience in developing procedures and protocols for repair of a broad range of medical equipment and devices.

[108] Conversation with G. Posdal.
[109] Conversation with G. Posdal.

135. More importantly, all of these purported "differences" raised by Dr. Howe relate not to the suitability of the cables of the device at issue for repair, but rather to the manner in which they are used and thus the eventual causes of a condition that requires repair. As I discussed above, Intuitive's own procedures regarding cable tensioning are relatively simple, and the tensioning of EndoWrist cables during both Intuitive's initial assembly and the Rebotix repair process is properly performed with suitable tools and fixturing. In contrast, the tensioning of flexible endoscope cables requires disassembly, access and soldering in tight spaces.[110]

136. Based on my review of the Rebotix cable tensioning process and my understanding of the cable repairs that SIS performs on other devices, the cable repairs that SIS has previously performed provide an adequate background to perform the cable tensioning of the Rebotix repair process. For example, repair of cabling in flexible endoscopes involves inspection, testing, and cable tensioning in tight spaces.[111] The cable tensioning of an EndoWrist that I observed at Rebotix, and that Intuitive engineers describe, can be performed with basic tools and fixturing, and appropriate training, as discussed above. All of these various repair applications require the technician to follow specific, detailed protocols. SIS has extensive experience in this field.

137. The purpose of cable tensioning is to avoid the results of a cable being too tight or too slack. When a cable is too tight, the wheels on the bottom of the EndoWrist require additional torque to move the cables, resulting in unintuitive or rough motion. Similarly, when a cable is too slack, the EndoWrist cable system does not accurately transmit the motions from the surgeon console to the end of the EndoWrist instrument, resulting in unintuitive motion. The only reason for identifying a specified tension number for the cable is that the tension value generally correlates to a device that is not exhibiting the results of the drive cable being too slack or too tight. However,

[110] Conversation with G. Posdal; SIS357887-SIS357893.
[111] Conversation with G. Posdal